X STOP® Interspinous Process Decompression (IPD) System

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician with appropriate training or experience.

Device Description
The X STOP® Interspinous Process Decompression System ("X STOP") is a titanium implant that fits between the spinous processes of the lumbar spine. It is made from Ti-6Al-4V Eli titanium alloy (ISO 5832/3) and consists of two components: a spacer assembly and a wing assembly (**Figure 1**).

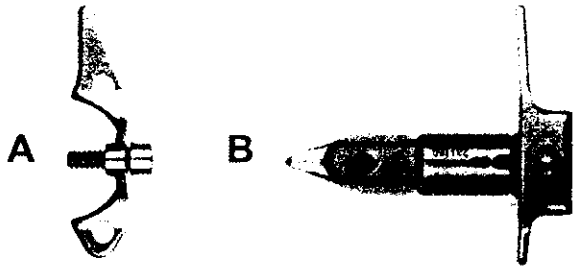

Figure 1. The X STOP is comprised of two components: A) a wing assembly and B) a spacer assembly. The X STOP is available in five (5) sizes: 6mm, 8mm, 10mm, 12mm and 14mm. The size refers to the minor diameter of the oval spacer on the spacer assembly of the X STOP.

Caution: The X STOP is manufactured from a titanium alloy which is known to produce MRI artifacts. Patients should be informed to disclose the presence of the X STOP prior to an MRI exam. Failure to do so may affect the quality of diagnostic information obtained from these scans. The X STOP is MRI safe.

Indication for Use
The X STOP Interspinous Process Decompression (IPD) System ("X STOP") is indicated for treatment of patients aged 50 or older suffering from neurogenic intermittent claudication secondary to a confirmed diagnosis of lumbar spinal stenosis (with X-Ray, MRI, and/or CT evidence of thickened ligamentum flavum, narrowed lateral recess and/or central canal narrowing). The X STOP is indicated for those patients with moderately impaired physical function who experience relief in flexion from their symptoms of leg/buttock/groin pain, with or without back pain, and have undergone a regimen of at least 6 months of nonoperative treatment. The X STOP may be implanted at one or two lumbar levels in patients in whom operative treatment is indicated at no more than two levels.

Contraindications
The X STOP is contraindicated in patients with:

- an allergy to titanium or titanium alloy;
- spinal anatomy or disease that would prevent implantation of the device or cause the device to be unstable *in situ*, such as:
    - significant instability of the lumbar spine, e.g., isthmic spondylolisthesis or degenerative spondylolisthesis greater than grade 1.0 (on a scale of 1 to 4);
    - an ankylosed segment at the affected level(s);
    - acute fracture of the spinous process or pars interarticularis
    - significant scoliosis (Cobb angle greater than 25 degrees);
- cauda equina syndrome defined as neural compression causing neurogenic bowel or bladder dysfunction;
- diagnosis of severe osteoporosis, defined as bone mineral density (from DEXA scan or some comparable study) in the spine or hip that is more than 2.5 SD below the mean of adult normals in the presence of one or more fragility fractures;
- active systemic infection or infection localized to the site of implantation.

Warnings

- The X STOP implant must be placed in the concavity between the spinous processes. Posterior positioning of the implant may result in dislodgement. If correct placement of the implant cannot be achieved due to variant anatomy, the surgeon should consider aborting the procedure because incorrect placement may result in device dislodgement, particularly if the patient experiences a traumatic event.

Precautions

- Radiological evidence of stenosis must be correlated with the patient's symptoms before the diagnosis can be confirmed.
- If the spinous processes at the affected level are not distracted in flexion, the X STOP may not be indicated.
- The safety and effectiveness of the X STOP device has not been studied in patients with the following conditions: axial back pain without leg, buttock or groin pain; symptomatic lumbar spinal stenosis at more than 2 levels; prior lumbar spine surgery; significant peripheral neuropathy; acute denervation secondary to radiculopathy; Paget's disease; vertebral metastases; morbid obesity; pregnancy; a fixed motor deficit; angina; active rheumatoid arthritis; peripheral vascular disease; advanced diabetes or any other systemic disease that may affect the patient's ability to walk.
- Surgeons should not implant the X STOP until receiving adequate training regarding surgical technique. Inadequate training may result in poor patient outcomes and/or increased rates of adverse events.
- A stress fracture of the spinous process may occur if strenuous physical activity is resumed too soon postoperatively.
- The X STOP is supplied sterile; however, the instruments are supplied non-sterile and must be properly cleaned and sterilized prior to surgery.

Potential Adverse Events

The following potential adverse events may occur as a result of interspinous process decompression with the X STOP; some of these adverse events were reported in the Pivotal Clinical Trial:

X STOP Related:

- implant dislodgement/migration;
- implant not positioned correctly;
- fracture of the spinous process;
- additional surgery, which could include removal of the X STOP implant;
- foreign body reaction;
- mechanical failure of the device;
- failure of the device/procedure to improve symptoms and/or function.

Surgery Related:

- reactions to anesthesia;
- myocardial infarction;
- infection;
- blood vessel damage/bleeding;
- deep vein thrombosis;
- hematoma;
- pneumonia;
- neurological system compromise;
- stroke;
- nerve injury or spinal cord damage;
- paralysis;
- thrombus formation;
- wound dehiscence or delayed healing;
- pain/discomfort at the operative site;
- death.

Note: Medication or additional surgery may be necessary to correct some of these potential adverse events.

Clinical Study

Study Design and Objectives

A prospective, randomized, controlled, multi-center clinical study was conducted in which 191 patients (100 X STOP, 91 control) were treated at 9 centers. The study objectives were to evaluate the safety and effectiveness of the X STOP in the treatment of neurogenic intermittent claudication secondary to mild or moderate lumbar spinal stenosis. The study was designed to determine if the X STOP treatment was superior to the control treatment, based on the criteria in **Table V** below.

Patients with neurogenic intermittent claudication secondary to mild or moderate lumbar spinal stenosis were eligible for enrollment. The inclusion criteria specified that patients be 50 years of age or older with leg, buttock, or groin pain with or without back pain that could be relieved during flexion. Eligible patients had to be able to sit for 50 minutes without pain, walk 50 feet or more, and have completed at least six months of nonoperative therapy. Stenosis was also confirmed by CT or MRI scans at one or two levels. Patients were excluded who had a fixed motor deficit; cauda equina syndrome; significant lumbar instability; previous lumbar surgery; significant peripheral neuropathy or acute denervation secondary to radiculopathy; significant peripheral vascular disease; scoliotic Cobb angle greater than 25 degrees; spondylolisthesis greater than grade I at the affected level; sustained pathologic fractures or severe osteoporosis of the vertebrae and /or hips; obesity; active infection or systemic disease such as AIDS, hepatitis, etc.; Paget's disease or metastasis to the vertebrae; or steroid use for more than one month within 12 months preceding the study.

Patients in the X STOP group had implantation of the device at one or two levels. Patients in the control group received at least one epidural steroid injection, and nonsteroidal anti-inflammatories (NSAIDs), analgesics, and physical therapy were prescribed as needed.

Using the Zurich Claudication Questionnaire (ZCQ), a validated outcomes instrument specific to lumbar spinal stenosis[1], data were collected prior to the initial treatment, and at 6 weeks, 6 months, 12 months, and 24 months following the initial treatment. Patients who required secondary intervention (i.e. device removal and/or laminectomy) were considered study failures. Secondary endpoint assessments included analgesic use, radiographic evaluation, back and leg pain assessments, and a general health index, the Medical Outcomes Study 36-Item Short Form Health Survey (SF-36).

Patient Accounting

A total of 191 patients were enrolled and treated in the X STOP clinical trial. This patient population, referred to as the "treated population" comprised 100 patients treated with the X STOP and 91 control patients who received nonoperative care. A total of 183 patients (96 X STOP, 87 control) were considered "evaluable," having survived through the 24 month postoperative follow-up.

Patient Demographics

Demographic information on the treated population is presented in **Table I**; **Table II** summarizes the number and locations of spinal levels implanted during the clinical trial.

Table I: Demographic Information – Treated Population

Variable	X STOP	Control	p-value
Age (yr.) Mean [Range]	70.0 [50-94]	69.1 [50-88]	0.513
Weight (lbs.) Mean [Range]	177.1 [105-265]	180.2 [98-293]	0.569
Height (in.) Mean [Range]	67.3 [56-74]	66.3 [56-75]	0.117
Gender: Male Female	57 (57.0%) 43 (43.0%)	46 (50.5%) 45 (49.5%)	0.387
Spondylolisthesis Present	35 (35.0%)	24 (26.7%)	0.272

P-value determined using Fisher exact test

Table II: Involved Levels – Treated Population

Variable	X STOP	
	n/N	%
Number of levels:		
1	64/100	64.0%
2	36/100	36.0%
Operated levels:		
L1-L2	0/136	0.0%
L2-L3	3/136	2.2%
L3-L4	43/136	31.6%
L4-L5	89/136	65.4%
L5-S1	1/136	0.7%

Adverse Events

Table III summarizes adverse events in the clinical trial that occurred perioperatively, or were causally or temporally related to treatment. Four patients died in each group during the course of the study. In the X STOP group, 2 patients died from cancer, 1 from pneumonia, and 1 from congestive heart failure (CHF)

[1] Stucki G, Liang MH, Fossel AH, et al. Relative responsiveness of condition-specific and generic health status measures in degenerative lumbar spinal stenosis. J Clin Epidemiol 1995.48(11):1369-78.

complications following implant surgery. In the control group, causes of death were cancer, pulmonary embolism following foot surgery, Parkinson's disease and myocardial infarction.

Table III: Summary of Adverse Events Related to X STOP, Lumbar Stenosis, Surgery, or Epidural Injections

Type of Adverse Event/Complication	Surgery/ Discharge		6 Weeks		6 Months		12 Months		24 Months		Overall*	
Treatment Group (X = X STOP; C = Control)	X	C	X	C	X	C	X	C	X	C	X (%)	C (%)
# of Patients at Each Follow-up Interval	100	91	100	91	99	91	98	89	96	83	(N = 100)	(N = 91)
DEVICE-RELATED ADVERSE EVENTS												
Device migration/dislodgement			1								1 (1.0%)	-
Malpositioned implant			1								1 (1.0%)	-
Spinous process fracture							1				1 (1.0%)	-
SUBTOTAL			2				1				3 (3.0%)	-
ADVERSE EVENTS RELATED TO LUMBAR SPINAL STENOSIS, SURGERY OR EPIDURAL INJECTION												
Coronary episode, ischemic	1										1 (1.0%)	0
Heart attack				1							0	1 (1.1%)
Epidural injection reaction		1		2						1	0	4 (4.4%)
Epidural injection failed (aborted)		1									0	1 (1.1%)
Hematoma at surgical site			1								1 (1.0%)	0
Incisional pain			1								1 (1.0%)	0
Pain and progressive neurological deficit				1							0	1 (1.1%)
Pain worsening in low back									1		1 (1.0%)	0
Pain, stenosis (progressed to laminectomy)**		2		3	3	9	1	4	2	8	6 (6.0%)	26 (28.6%)
Pulmonary edema			1								1 (1.0%)	0
Respiratory distress	1										1 (1.0%)	0
Wound dehiscence			1								1 (1.0%)	0
Wound swelling	1										1 (1.0%)	0
SUBTOTAL	3	4	4	7	3	9	1	4	3	9	14 (14.0%)	33 (36.3%)
TOTAL # of Events	3	4	6	7	3	9	2	4	3	9	17 (17.0%)	33 (36.3%)

*# Events = # Patients
**The study protocol did not specify criteria for proceeding to laminectomy in either treatment group.
Note: Time intervals for this and other tables in the Summary of Safety and Effectiveness are defined as follows: 6 weeks = 1 - 42 days; 6 months = 43 - 182 days; 12 months = 183 - 365 days; 24 months ≥ 366 days.

Table IV lists post-implantation interventions in the X STOP group and surgical procedures in the control group. One implant was removed after it dislodged subsequent to a fall. Six X STOP patients and 24 control patients underwent a laminectomy for continued stenosis symptoms, based on a determination made by the individual physician and patient. (The study protocol did not specify criteria for proceeding to laminectomy.)

Table IV: Summary of Surgical Interventions

Type of Intervention	Surgery/ Discharge		6 Weeks		6 Months		12 Months		24 Months		Overall*	
Treatment Group (X = X STOP; C = Control)	X	C	X	C	X	C	X	C	X	C	X (%)	C (%)
# of Patients at Each Follow-up Interval	100	91	100	91	99	91	98	89	96	83	(N = 100)	(N = 91)
IMPLANT REMOVAL and/or LAMINECTOMY												
Implant removal alone			1								1 (1%)	NA
Laminectomy**				2	2	10	2	4	2	8	6 (6%)	24 (26%)
REOPERATION												
Drainage of hematoma			1								1 (1%)	-
Aspiration of wound swelling			1								1 (1%)	-
Debridement and secondary wound closure			1								1 (1%)	-
TOTAL # of Interventions	-	-	4	2	2	10	2	4	2	8	10 (10%)	24 (26%)

* # of interventions = # of patients
**All X STOP patients who underwent laminectomy had implant(s) removed at time of laminectomy

Overall Treatment Success

Primary Effectiveness Endpoint
The primary effectiveness endpoint was overall treatment success at the 24 month follow-up, which required all of the following conditions: ZCQ success, no additional operation for stenosis symptoms, and for X STOP patients only, distraction maintained at 24 months, no implant dislodgement, and no device-related complications. **Table V** below summarizes the success criteria for each group.

Table V: Components of Overall Treatment Success

Criterion	X STOP	Control
ZCQ Success: • Improvement in Physical Function (by > 0.5 pts) • Improvement in Symptom Severity (by > 0.5 pts) • "Satisfied" or "Somewhat Satisfied" (< 2.5 pts)	X	X
No additional surgery for lumbar stenosis	X	X
Maintenance of distraction	X	
No dislodgement of the implant	X	
Absence of implant-related complications	X	

Evaluable Population

Success rates were variable across the nine investigational sites, with one site showing a significantly higher percentage of patients who had overall treatment success. The X STOP success rates were greater than the control success rates at all nine centers that participated in the clinical trial. **Table VI** shows success rates calculated in two ways—for all sites, and excluding the investigational site with the highest success rates (Site 01/04).

Table VI: Treatment Success at 24 Month Follow-Up – Evaluable Population†

Outcome Parameter	All Sites			All Sites Excluding Site 01/04		
	X STOP n/N (%)	Control n/N (%)	p-value	X STOP n/n (%)	Control n/n (%)	p-value
ZCQ Success	45/96 (47%)	4/87 (5%)	<0.001*	28/76 (37%)	2/70 (3%)	<0.001*
No additional surgery for lumbar stenosis[a]	86/96 (90%)	57/87 (66%)	<0.001*	66/76 (87%)	44/70 (63%)	<0.001*
Maintained distraction[b]	81/96 (84%)	NA	NA	61/76 (80%)	NA	NA
No dislodgement[c]	92/96 (96%)	NA	NA	72/76 (95%)	NA	NA
Absence of implant-related complications[d]	90/96 (94%)	NA	NA	71/76 (93%)	NA	NA
Overall Treatment Success[e]	**41/94 (44%)**	**4/87 (5%)**	**<0.001***	**24/74 (32%)**	**2/70 (3%)**	**<0.001***

†Evaluable population was defined as all treated patients who survived through 24 month follow-up

*Indicating a level of significance < 0.05; P-values determined using Fisher exact test

[a]The X STOP group includes 6 patients who underwent device removal and laminectomy; 1 patient who underwent device removal only; and 3 patients who did not have 24 month outcome data available and were therefore classified as device failures.

[b]The X STOP group includes 4 patients who failed to maintain distraction; and 11 patients who had insufficient data at 24 months to determine maintenance of distraction; among the 85 patients for whom sufficient data were available, distraction was maintained at 96% of the levels measured (i.e., 109 of 113 implanted levels)

[c]The X STOP group includes 1 patient in whom the implant dislodged after a fall; and 3 patients who did not have 24 month outcome data available and were therefore classified as device failures.

[d]The X STOP group includes 1 patient with device dislodgement; 1 patient with an asymptomatic spinous process fracture; 1 patient with malpositioned implants; and 3 patients who did not have 24 month outcome data available and were therefore classified as device failures.

[e]Two X STOP patients were removed from the overall treatment success analysis because they received post-operative epidural injections following motor vehicle accidents.

Indicated Population (subset of Evaluable Population)

Within the evaluable population, the subset of patients most likely to benefit from the X STOP device was identified (via post-hoc analysis) as those with moderately impaired physical function at baseline. Within this indicated population (defined as patients having baseline ZCQ PF scores > 2.0), success rates in each ZCQ domain as well as overall success were statistically significantly higher in the X STOP group when compared to the control group. Success rates were calculated for all sites, and excluding the investigational site with the highest success rates (Site 01/04).

In the indicated population, overall treatment success at all sites was 54% for the X STOP group compared to 6% for the control group (p<0.001). Excluding Site 01/04, overall treatment success was 42% for the X STOP group compared to 4% for the control group (p<0.001).

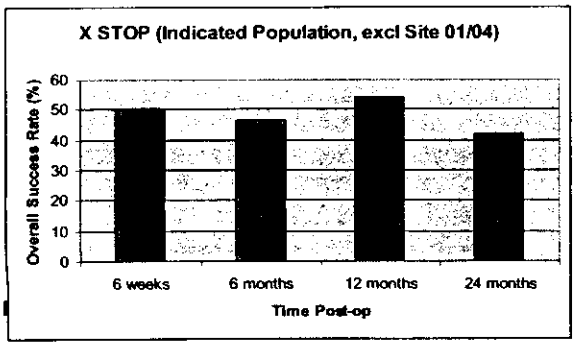

Figure 2. This graph illustrates overall success rates for the indicated population (excluding Site 01/04) at each of the post-operative follow-up intervals – 6 weeks, 6 months, 12 months, and 24 months. (Note: Two X STOP patients were removed from the overall treatment success analysis at 24 months because they received post-operative epidural injections.)

Effectiveness of the device beyond 24 months post-implantation has not been demonstrated.

Secondary Endpoints and Analyses
SF-36 domain scores were compared between the X STOP and control groups using an ANOVA ($p<0.05$). The mean scores for the Physical Component Summary (PCS) and Mental Component Summary (MCS) for the X STOP and control patients comprising the indicated population, at baseline and 24 month follow-up, are shown in **Table VII**. There were no statistically significant differences in mean baseline SF-36 domain scores between the X STOP and control groups. However, the mean change score for the PCS at the 24-month follow-up was statistically significantly higher in the X STOP group compared to the control group.

Table VII: SF-36 Domain Scores at Baseline and 24 Month Follow-up – Indicated Population

Domain	X STOP		Control	
	Preop	24 mo	Preop	24 mo
Physical Component Summary (PCS)	**26.9**	**39.6**	**26.9**	**29.1**
Mental Component Summary (MCS)	**49.6**	**53.9**	**48.9**	**52.5**

In vivo Clinical Radiographic Study
Following the pivotal clinical trial, a prospective, nonrandomized clinical radiographic study was undertaken to evaluate the pre- and postoperative changes in the dimensions of the spinal canal and neural foramen during flexion and extension in LSS patients who received the X STOP implant at a single European clinical site.

Measurements were made from 37 levels in 26 patients. Fifteen patients were implanted at a single level and 11 patients were implanted at two levels. The mean age was 71.3 years (range 56.1 to 94.0). MRI scans were acquired preoperatively and 6 months following X STOP surgery. Each patient was scanned prior to treatment and at 6 months after treatment while sitting in a 0.6 Tesla positional MRI scanner (Fonar, Melville, NY) in the flexed and extended positions. The intervertebral angle, foramen area, and canal area were digitally measured from each scan using image analysis software (OSIRIS 4, University Hospital of Geneva, Switzerland).

Clinical outcomes data at 6 months follow-up were available for 24 of the 26 patients. Of these 24 patients, 11 satisfied the criteria for patient success (11/24; 46.0%) where success was defined as clinically significant improvement in Physical Function and Symptom Severity scores compared to baseline (≥ 0.5 point change) in patients who were "satisfied" or "very satisfied" as self-reported using the Zurich Claudication Questionnaire (ZCQ).

Pre- and postoperative radiographic changes, measured on an individual patient basis, are described below:

- *Flexion-Extension Range of Motion*: Ten of the 26 patients (38%) exhibited a decreased ROM at all implanted levels following X STOP implantation; these 10 patients included three who were treated at two levels. Seven of the 11 patients (64%) treated at two levels exhibited decreased ROM at one treated level, and either no change or an increased ROM at the other level. In total, 20 of the 37 implanted levels (54%) exhibited a decreased ROM.
- *Foramen Area*: Twenty of the 26 patients (77%) exhibited an increased foramen area at all implanted levels following X STOP implantation. An additional three patients who were treated at two levels exhibited an increased foramen area at one of the two implanted levels. In total, 31 of the 37 implanted levels (84%) exhibited an increased foramen area.
- *Canal Area*: Canal area measurements were available for 24 of the 26 patients and 35 of the 37 levels. Fifteen of the 24 patients (63%) exhibited an increased canal area at all implanted levels following X STOP implantation. One patient who was treated at two levels exhibited an increased canal area at one level, but complete canal area measurements were not available for the other level (which showed decreased foramen area). In total, 26 of the 35 implanted levels (74%) exhibited an increased canal area.

A correlation between these radiographic changes and clinical outcomes was not demonstrated at six months post-implantation.

(2)

The X STOP is not re-usable.

How Supplied
The X STOP implant is supplied **sterile**. The X STOP instruments are supplied **non-sterile** and must be sterilized prior to use.

X STOP Implant Sterilization
X STOP implants are supplied sterile and should be handled in a manner to avoid contamination. The X STOP is packaged in its own sterilization cassette that is double-pouched. In the event of damage to the sterile packaging or inadvertent contamination, implants maybe steam sterilized. The sterilization cassette with the X STOP implant inside must be placed in a sterilization pouch before being sterilized. The X STOP can be re-sterilized in its sterilization cassette up to five times using one of the following parameters:

Method	Cycle	Temperature	Exposure Time
Steam	Gravity	273°F (134°C)	20 Minutes
Steam	PreVacuum	270°F (132°C)	8 Minutes

X STOP Instrument Sterilization

*Caution: Instruments for implantation of the X STOP are provided **non-sterile** and must be sterilized prior to use.*

Cleaning Instruments Prior to Sterilization
The X STOP instruments should be wiped with a sponge moistened with sterile water prior to being sterilized. Saline causes corrosion and deterioration of the instrument surfaces.

The cleaning methods described below will provide protection from cross-contamination as well as prevent damage to the instruments and injury to the cleaner:

1. Clean the instruments as soon as possible after use. Do not allow blood and debris to dry on the instruments.
2. Place the instruments in a basin filled with water and enzymatic agent, cover and proceed to the decontamination area.
3. Clean the instruments using warm, soapy water with a sponge and/or a soft-bristle brush with particular attention to serrations and joints. Scrub the pins and sliding mechanisms with a soft-bristle brush. There should be no visible tissue or fluid on the instrument.

Cleaning the Spacer Assembly Insertion Instrument
4. The spacer assembly insertion instrument has a cleaning slot located on the shaft of the instrument, in front of the knob, as shown in **Figure 3**.
5. Flush the internal chamber repeatedly with cleaning solution, sliding the knob on the handle back and forth as the fluid runs through the instrument. This process should be repeated until the fluid exiting the tip of the instrument runs clear. Flush the cleaning solution completely from the chamber with warm water.
6. Clean the external portion of the instrument using warm, soapy water, and a sponge. There should be no visible tissue or fluid on the instrument.

Cleaning the Wing Assembly Insertion Instrument
7. The wing assembly insertion instrument must be disassembled prior to cleaning. Unscrew the endcap of the instrument, located at the proximal end of the handle until the threads disengage from the handle. See **Figure 4**.
8. Remove the hex drive system by sliding it from the proximal end of the instrument. See **Figure 5**. Scrub and rinse the hex drive system knob, and both the internal and external surfaces of the handle assembly. There should be no visible tissue or body fluid remaining. Flush the cleaning solution completely from the chamber with warm water.
9. Re-assemble the instrument:
   - Step 1: Place the knob into the slot on the top of the handle assembly as shown in **Figure 5**.
   - Step 2: Slide the hex drive assembly into the internal chamber of the handle assembly. Slight manipulation of the hex drive assembly may be required for it to pass through the knob.
   - Step 3: Tighten the endcap hand tight.
   - Step 4: Actuate the knob back and forth to ensure proper function. The hex drive should retract when the knob is actuated.

Figure 3. The spacer assembly insertion instrument

Figure 4. The wing assembly insertion instrument

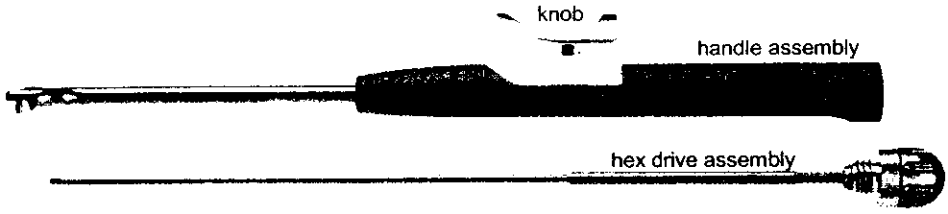

Figure 5. The disassembled wing assembly insertion instrument

Sterilization Procedure
The X STOP instruments are provided non-sterile and must be steam sterilized prior to use, using one of the following parameters:

Method	Cycle	Temperature	Exposure Time
Steam	Gravity	273°F (134°C)	20 Minutes
Steam	PreVacuum	270°F (132°C)	8 Minutes

Storage
The X STOP should remain stored in a clean area until ready for use.

Implantation Procedure
Refer to Physician's Guide for detailed information.

Returned Goods Policy
For detailed information on the St. Francis Medical Technologies, Inc. return goods policy, please contact your local representative.

Manufactured by
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